# MEDWATCH

FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by us
distributors and ma
MANDATOR

*3118381-8-00-01*

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FDA Use Only

## A. Patient information

| 1. Patient identifier | 2. Age at time of event: | 3. Sex | 4. Weight |
|---|---|---|---|
| UNKNOWN | 17 Year(s) or Date of birth: | ☐ female ☒ male | ____lbs or UNK ____kgs |
| In confidence | | | |

## B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death (mo/day/yr)
- ☐ life-threatening
- ☒ hospitalization - initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other:

3. Date of event (mo/day/yr) UNK

4. Date of this report (mo/day/yr) 08/12/98

5. Describe event or problem

A report from a medical toxicologist of a case involving a 17 year old male who was hospitalized with elevated liver function tests,renal insufficiency,elevated lipase,rhabdomyolysis,and thrombocytopenia. A urine toxicology screen revealed acetaminophen,diphenhydramine, and Tramadol.A plasma APAP level was 6 ug/ml. The patient has been taking Tramadol for pain for one month.In addition, he was taking Tylenol PM (acetaminophen/diphenhydramine) at HS and occasional Tylenol (acetaminophen) for aches and pains. No doses provided.The initial liver function tests,elevated lipase, thrombocytopenia and evidence of rhabdomyolysis [illegible]lined. A modest elevation of LFT's persists (approx. 400 [illegible]e), the creatinine remains elevated and the patient has [illegible]to undergo repeat dialysis.This patient has a history of prior brain injury.

Follow-up received 06-AUG-98 from toxicologist:The patient is now off dialysis with recovering renal function, and is in the neuro rehabilitation unit improving.As of 29-JUL-98 ALT was continuing in the "100's".Provided indication for use and concomitant medication information.

6. Relevant tests/laboratory data, including dates

plasma APAP level 6 ug/ml, elevated creatinine (NOS), no initial LFT's provided- subsequent LFT (400 range)- unspecified

Follow-up received 06-AUG-98: ALT continues in "100's"

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

history of prior brain injury

Follow-up received 06-AUG-98:headaches,leg cramps,backache

## C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 TRAMADOL (TRAMADOL)
#2 TYLENOL PM (ACETAMINOPHEN/DIPHENHYDRAMINE)

2. Dose, frequency & route used
#1 Unknown, Unknown, ORAL
#2 Unknown, hs, ORAL

3. Therapy dates (if unknown, give duration) (mm/dd/yy (or best estimate))
#1 ??/??/?? - ??/??/??
#2 ??/??/?? - ??/??/??

4. Diagnosis for use (indication)
#1 pain, including headaches, leg cramps, backache
#2 sleep disturbance

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no UNK ☒ doesn't apply
#2 ☐ yes ☐ no UNK ☒ doesn't apply

6. Lot # (if known)
#1 UNK
#2 UNK

7. Exp. date (if known)
#1 UNK
#2 UNK

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no UNK ☒ doesn't apply
#2 ☐ yes ☐ no UNK ☒ doesn't apply

9. NDC # - for product problems only (if known)
NA

10. Concomitant medical products and therapy dates (exclude treatment of event)
1) NONE ??/??/?? - ??/??/??

## G. All manufacturers

1. Contact office - name/address (& mfring site for devices)
R. W. JOHNSON PHARM. RESEARCH INSTITUTE
DIV. OF ORTHO PHARMACEUTICAL CORPORATION
ROUTE 202, P.O. BOX 300
RARITAN NJ 08869-0602

(Informing unit)

2. Phone number
(908) 704-4600

3. Report source (check all that apply)
- ☐ foreign
- ☐ study
- ☐ literature
- ☐ consumer
- ☒ health professional
- ☐ user facility
- ☐ company representative
- ☐ distributor
- ☐ other:

4. Date received by manufacturer (mo/day/yr)
08/06/98

5. (A) NDA # 20-281
IND #
PLA #
pre-1938 ☐ yes
OTC product ☐ yes

6. If IND, protocol #

7. Type of report (check all that apply)
- ☐ 5-day ☒ 15-day
- ☐ 10-day ☐ periodic
- ☐ Initial ☒ follow-up # 1

8. Adverse event term(s)
1) RENAL FAILURE ACUTE
2) RHABDOMYOLYSIS
3) HEPATIC ENZYMES INCREASED
4) THROMBOCYTOPENIA
5) ENZYME ABNORMALITY

9. Mfr. report number
980713-107012507

## E. Initial reporter

1. Name, address & phone #
[redacted] TOXICOLOGIST
[redacted] CENTER
Phone # [redacted]

[illegible] 1998

2. Health professional? ☒ yes ☐ no

3. Occupation
Physician

4. Initial reporter also sent report to FDA
☐ yes ☐ no ☒ unk

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Form 3500A Facsimile

Approved by FDA on 10/29/93

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| In confidence | | ☐ female ☐ male | ____lbs or ____kgs |

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- ☐ hospitalization - initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ____

3. Date of event (mo/day/yr)

4. Date of this report (mo/day/yr)

5. Describe event or problem

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

## C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#3 TYLENOL (ACETAMINOPHEN)
#4

2. Dose, frequency & route used
#3 Unknown, PRN, Unknown
#4

3. Therapy dates (if unknown, give duration) (from/to (or best estimate))
#3 ??/??/?? - ??/??/??
#4

4. Diagnosis for use (indication)
#3 aches and pains
#4

5. Event abated after use stopped or dose reduced
#3 ☐ yes ☐ no UNK ☒ doesn't apply
#4 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#3 UNK
#4

7. Exp. date (if known)
#3 UNK
#4

8. Event reappeared after reintroduction
#3 ☐ yes ☐ no UNK ☒ doesn't apply
#4 ☐ yes ☐ no ☐ doesn't apply

9. NDC # - for product problems only (if known)
NA

10. Concomitant medical products and therapy dates (exclude treatment of event)

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- ☐ company representative
- ☐ distributor
- ☐ other: ____

4. Date received by manufacturer (mo/day/yr)

5. (A)NDA # ____
IND # ____
PLA # ____
pre-1938 ☐ yes
OTC product ☐ yes

6. If IND, protocol #

7. Type of report (check all that apply)
☐ 5-day ☐ 15-day ☐ 10-day ☐ periodic ☐ Initial ☐ follow-up # ____

8. Adverse event term(s)

9. Mfr. report number

## E. Initial reporter

1. Name, address & phone #

20 1998

2. Health professional? ☐ yes ☐ no

3. Occupation

4. Initial reporter also sent report to FDA ☐ yes ☐ no ☐ unk

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